K 001248

IMAGING SCIENCES INTERNATIONAL INC.

910 North Penn Road
Hatfield, PA 19440

Phone (215) 997-5666
Fax (215) 997-5665, 5667

MAY - 4 2000

510 (k) Summary

Submitters Information

Name:	Imaging Sciences International Inc.
Address:	1910 North Penn Road Hatfield PA, 19440
Phone Number:	215-997-5666
Fax Number:	215-997-5665
Person To Contact:	Robert E. Hay Radiation Safety Officer
Date Of Summary:	April 14, 2000
Trade Name Of The Device:	Multi-Pulse 2000
Common Or Usual Name:	Panoramic X-Ray
Classification Name:	X-Ray, Tomographic

Substantial Equivalence Claim: The Imaging Sciences International Inc. Multi-Pulse 2000 X-Ray Machine with Optional Cephalometric Attachment is substantially equivalent to the J. Morita USA Inc. Versaview Panoramic-Cephalometric X-Ray Machine.

Description Of The Device: The Imaging Sciences International Inc. Multi-Pulse 2000 X-Ray Machine with Optional Cephalometric Attachment is a free standing Panoramic X-Ray machine that may also be affixed to the wall during installation for added stability. All of the Multi-Pulse 2000 functions such as kVcp, mA, exposure time and all motor functions are computer controlled. There is a touch panel with display that will show the various technique factors.

Intended Use Of The Device: The Imaging Sciences International Inc. Multi-Pulse 2000 X-Ray Machine with Optional Cephalometric Attachment is a multifunction computer controlled X-Ray Machine. This device has the ability to provide Panoramic and Cephalometric images of the head and neck region. The operators manual describes the computerized operator interface for selecting and executing the various radiographic procedures.

The Panoramic function of this unit produces the same standard Panoramic image as numerous other units in use for past several decades.

The Cephalometric function of this unit produces the same standard Panoramic image as numerous other units in use for past several decades.

Technological Characteristics Of The Device: The Multi-Pulse 2000 with Optional Cephalometric Attachment X-Ray Machine technology is based on the Keystone X-Ray ***Intrex VSK***, 510 (k) Number K931486.

The basic power supply consists of a full wave bridge rectifier, so connected that it may be operated on either 120 VAC or 220 VAC, 50 - 60 Hz power lines. This is accomplished by changing jumpers in the power supply.

At the output of the bridge rectifier, two very high capacity 250V filter capacitors smooth the rectified power, which is then presented to a voltage regulator, consisting of five transistors, amplifiers and a reference diode. This regulator regulates the voltage applied to a four diode transistor inverter chopper.

Another low voltage power supply, with its step down transformer, bridge rectifier, and associated filters, supply power to another regulator and a logic board, so connected as to control the technique factors and the "on - off" exposure of the X-Ray System.

The inverter is supplied by a 20 KHz signal that is developed on the logic board. This 20KHz alternately turns on and off the inverter to chop the DC power that has been generated in the power supply.

The 20KHz square wave is now transformed into 200 volt positive and negative pulses, this signal is then sent to the tubehead. In the tubehead the signal is supplied to a power output transformer, which raises the 200 volts to 6,000 volts. This 6,000 volts is now applied to a plus and minus multiplier PC boards. With its associated diodes and capacitors, the multiplier boards raise the 6,000 volt square wave to plus 35,000 and minus 35,000 volts. An X-Ray tube is placed between the two multiplier board outputs creating a potential across the X-Ray of 70,000 volts. The 20 KHz, 200 volt square wave may be adjusted upward and downward to create a kVp range from 50 kVcp to 90 kVcp in 4 kVcp increments.

The filament of the X-Ray tube is also heated by the 20 KHz signal taken directly from the oscillator on the logic board. A rheostat is placed in series with the filament transformer, so it may be shunted out for fast heating of the filament, and switched back in during the exposure.

A voltage divider in the multiplier circuit of the tubehead allows the monitoring of the kVp. A current sample obtained from the primary of the power transformer allows the mA to be proportionately monitored within a 10% accuracy.

Two timers are included. One of the timers delays the exposure turn on, until the filament has reached sufficient operating temperature. The second timer times the length of the desired exposure. The exposure time can be programmed from 0.01 to 2.0 seconds in increments of 0.01 seconds.

In operation when, the exposure switch push button is depressed, the delay timer starts counting down a preprogrammed time that allows the filament to heat up to its proper temperature. When the delay timer has timed out the countdown of the exposure timer starts. At the end of the exposure, the exposure timer ceases operation, thereby shutting down both the high voltage anode and filament supplies, terminating the exposure.

Assessment of Non-Clinical Performance: During the evaluation, the Multi-Pulse 2000 X-Ray Machine with Cephalometric Attachment produced radiographs of a step wedge and a phantom that were comparable with the J. Morita USA Inc. Versaview Panoramic-Cephalometric X-Ray Machine.

Conclusions of Non-Clinical Performance: The performance of the Imaging Sciences International Inc. Multi-Pulse 2000 X-Ray Machine with Cephalometric Attachment during the non-clinical evaluation would indicate that the system is substantially equivalent mechanically, electrically and radiographically to the J. Morita USA Inc. Versaview Panoramic-Cephalometric X-Ray Machine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2000

Robert E. Hay
Radiation Safety Officer
Quality Management Representative
Imaging Sciences International, Inc.
910 North Penn Road
Hatfield, PA 19440

Re: K001248
Multi-Pulse 2000, Panoramic X-Ray
Dated: April 14, 2000
Received: April 18, 2000
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Mr. Hay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): _____

Device Name: _____

Indications For Use:

Multi-Pulse 2000
Panoramic X-Ray Unit
Indications for Use

The Imaging Sciences International Inc. Multi-Pulse 2000 Panoramic X-Ray unit is a microprocessor controlled Tomographic X-Ray device for taking radiographs of the dental anatomy. This device has the ability to produce Panoramic Tomographic images. The operator's manual describes the operator touch panel interface for selecting and executing the various radiographic procedures.

The panoramic function of this unit produces the same standard panoramic image as numerous other units in use for past several decades.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001248

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known):_____

Device Name:_____

Indications For Use:

Multi-Pulse 2000
Panoramic X-Ray Unit
With Optional Cephalometric Attachment
Indications for Use

The Imaging Sciences International Inc. Multi-Pulse 2000 Panoramic X-Ray unit / with optional Cephalometric attachment is a microprocessor controlled X-Ray device for taking static radiographs of the Skull. This device has the ability to produce Lateral, Anterior-Posterior, Posterior-Anterior, Submentovertex, Waters View and the Towne Projection images of the Skull. The operator's manual describes the operator touch panel interface for selecting and executing the various radiographic procedures.

The Cephalometric function of this unit produces the same standard Cephalometric images as numerous other units in use for past several decades.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001248

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use_____

(Optional Format 1-2-96)